APR 0 7 2014

510(k) Summary

Device Trade Name: Threaded PEEK K-Wire

Manufacturer:
MTP Solutions LLC
124 South 600 West, Suite 100
Logan, UT 84321

Contact:
Mr. Robert Hoy
Director of Technical & Clinical Research
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Prepared by:
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Date Prepared: April 4, 2014

Common Name: Threaded Fixation Pin

Classification: 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener

Class: II

Product Code: MBI

Indications for Use:
The Threaded PEEK K-Wire is intended for use with suture in metatarsal ligament and tendon repairs.

Device Description:
Threaded K-Wire is manufactured from PEEK and is 1.6 mm in diameter over its entire length. Both ends of the K-Wire are threaded, providing for two implants per device. The diameter of the pin allows it to function well with standard K-Wire drivers and the device is meant to be trimmed to length once in place.

Predicate Devices:
The Threaded PEEK K-Wire is substantially equivalent to the Arthrex, Inc. PushLock (K101679, K082810, K071177, K063479, K061863, K051219) with respect to its indications for use, principles of operation, materials and design.

Technological Characteristics Comparison:
The Threaded PEEK K-wire is similar to the Arthrex PushLock with regards to principles of operation, materials and design with both the subject and predicate devices being manufactured from PEEK, cylindrical in shape with threads or ribs and acting to compress suture against a bone tunnel wall. There are no substantial differences in technological characteristics between the devices and as such the Threaded PEEK K-Wire introduces no new issues of safety or effectiveness.

Nonclinical Testing:
All necessary testing has been performed for the Threaded PEEK K-Wire to assure substantial equivalence to the predicate and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. Clinical data were not needed to support the safety and effectiveness of the subject device.

The device design was qualified through the following tests:

- Simulated use Testing
- Ultimate Strength Testing
- Initial Stiffness Testing
- Suture Strength Testing
- Cyclic Testing

The results of this testing demonstrate that the Threaded PEEK K-Wire performs as intended and demonstrate that the Threaded PEEK K-Wire is substantially equivalent to its predicates.

Conclusion:
The Threaded PEEK K-Wire met all specified criteria performing as intended and did not raise any new issues of safety or effectiveness. The Threaded PEEK K-Wire is substantially equivalent to the Arthrex PushLock predicate with regards to indications for use, as the Threaded PEEK K-Wire indications for use represent a subset of the Arthrex PushLock indications for use. The fundamental scientific technology of the Threaded PEEK K-Wire is the same as described in the Arthrex PushLock predicates. Therefore, the Threaded PEEK K-Wire is substantially equivalent to the Arthrex, Inc. PushLock (K101679, K082810, K071177, K063479, K061863, K051219).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 7, 2014

MTP Solutions LLC
Mr. Robert Hoy
Director of Technical & Clinical Research
124 South 600 West, Suite 100
Logan, Utah 84321

Re: K133235
Trade/Device Name: Threaded PEEK K-Wire
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 28, 2014
Received: March 4, 2014

Dear Mr. Hoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133235

Device Name: Threaded PEEK K-Wire

Indications for Use:

The Threaded PEEK K-Wire is intended for use with suture in metatarsal ligament and tendon repairs.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

Elizabeth D. Frank -S

Division of Orthopedic Devices